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EXAMINER

GORDON, BRIAN R

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,498

Applicant(s)

KIRCHER ET AL.

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6. 6) ☐ Other: _____

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

1. The disclosure is objected to because of the following informalities: Summary of Invention and Brief Description of Drawings section headings are missing.

Appropriate correction is required.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. Claim 11 is objected to because of the following informalities: It appears as if claim 11 should read "said apparatus is adapted to be used by users in at least two locations". Appropriate correction is required.

OK

Drawings

4. Figures 2-3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

OK

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 10, 24-27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. US 5,228,485.

Lewis et al. discloses an invention that generally relates to systems for transferring fluids from individual source containers to a receiving container, and more

specifically relates to systems for transferring liquid drugs from individual vials, bottles, or bags to a single solution bag or bottle for administration to a patient.

In hospitals, it is frequently necessary to provide solutions for intravenous administration to a patient which contain a variety of drugs in a single solution container. A common example of such a need arises when a patient is receiving all of his nutritional needs intravenously. In this situation, the patient will typically receive a basic solution containing amino acids, dextrose, and fat emulsions which provide a major portion of the patient's nutritional needs (prescriptions). However, this solution is insufficient to maintain a patient for an extended period of time. Therefore, a typical total parenteral solution includes as many as eight to twelve additional additives. The additives are typically minute quantities of vitamins, minerals, electrolytes, etc. Therefore, when a pharmacist is preparing a solution for total parenteral nutrition, it is necessary for the pharmacist to individually add each of the additional additives to a solution container after the base solutions have been added. This is typically done with individual syringes and requires a relatively long time on the part of a pharmacist to accurately add all additives to each of the required additives.

An object of the invention is to provide a means for periodically flushing the measuring chamber described above to rinse the chamber of any incompatible drugs. In accordance with the invention, a device 10 (FIG. 1) is provided for accurately transferring individual doses of separate fluids from individual source containers 12. Each individual source container may contain a different fluid 14. In some cases, the fluid in one container may be incompatible with fluids contained in other source

containers. According to the invention, fluid is transferred from each source container 12 through a separate individual fluid conduit 16 to a single chamber 18. The chamber 18 is suspended from a load cell assembly 20. The load cell 20 constantly weighs the total weight of the chamber to develop an output signal which is indicative of the amount of fluid in the chamber 18 at any given time.

The device comprises a control means that may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber if the first and second fluids are compatible with each other and there is sufficient empty space remaining in the chamber to receive the entire amount of the second fluid to be dispensed. The control means will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids are incompatible with each other, when properly programmed, or if insufficient room exists in the chamber (which inherently implies that the device may be programmed to compare pharmaceutical components relative to one another allowing the order of dispensing to be determined).

After a transfer set has been installed in the device, the operator is then ready to program the device to indicate the amount and type of each fluid to be transferred from each of the individual source containers into the receiving container. Information can be input into the device from one of two sources. One source of entering information into the device is a keyboard entry device, illustrated in FIG. 22.

When the device is turned on, a system of internal checks is automatically performed by the control means 32. In the preferred embodiment of the invention, two microprocessors are used in the control means 32. While a variety of microprocessors

can be used, in one embodiment of the invention, an Intel 8031 microprocessor can be used for both of the microprocessors. One microprocessor serves as a master microprocessor and another microprocessor serves as a pumping control microprocessor. A simplified block diagram of a typical microprocessor is illustrated in FIG. 23. As can be seen in this figure, a typical microprocessor includes an internal random access memory 222 and a plurality of in/out (I/O) ports 224. The microprocessors include a variety of hardware registers which can be programmed to perform special functions. In the preferred embodiments of the subject invention, the special function hardware registers 226 may include serial interface registers 228, timer/counters 230, and a stack pointer 232. Each of these aspects of the microprocessor as used in the preferred embodiment of the subject invention will be discussed in greater detail below. In addition to the internal features of a typical microprocessor as briefly described above, additional external hardware is present in a typical microprocessor control device. For example, an external RAM 234, external in/out ports 236(LAN connection), and a programmable memory (ROM) 238 are required to allow a microprocessor to perform the desired functions in accordance with the invention.

FIG. 26 illustrates a display panel for displaying volumetric and specific gravity information for each source container. The display panel displays the specific gravity as programmed by an operator for a particular source container as illustrated by LCD display panel 250. The volume of fluid to be transferred from a specific source container to the receiving container as programmed by an operator is illustrated by another LCD

display panel 252. Each individual source container has separate LCD display panels 250 and 252 for displaying the specific gravity and volumetric information for each source container.

The programmer may either enter the volume or the specific gravity of the fluid to be transferred. Typically, during initial set up of the device, the specific gravity for each source container will be initially programmed by the operator.

If the pump control microprocessor is ready to receive data, the master microprocessor computes (conversion) the weight of fluid to be transferred from each individual source container to the receiving container given the volume and specific gravity information input in the device during the keyboard entry mode. This computation is essentially identical to the computations described in U.S. Pat. No. 4,513,796 entitled "High Speed Bulk Compounder" issued Apr. 30, 1985. This application is incorporated herein by reference. The pump control routine checks to see if any of the information entered by the operator is out of a predetermined range. For instance, in the preferred embodiment of the invention, the allowable range for specific gravity is between approximately 0.5 and 3.0. The minimum volume to be transferred has to be, for example, at least one milliliter in the preferred embodiment of the invention. If any of the information is determined to be outside of these ranges, the pump control routine notifies (alarms) the operator by causing the display 250 or 252 (FIG. 26) which is out of range to flash. This is illustrated by block 302 in FIG. 28.

The drain routine is simply a series of checks to determine if the chamber needs to be drained. The first check performed by the drain routine is to determine if the last

source container has been pumped. This check is illustrated by decision diamond 506 in FIG. 36. If the last source container has not been pumped, the drain routine next checks to see if a rinse is to follow the source container that was just pumped. This check is illustrated by decision diamond 508. Normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped. The next check performed by the drain chamber routine is to determine if the next source container to be pumped is supposed to be followed by a rinse. This is illustrated by decision diamond 510. In the preferred embodiment of the invention, if the next source container is to be followed by a rinse, then a drain operation will occur prior to filling the chamber with that fluid.

Claim Rejections - 35 USC § 103

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 5-23 and 28, 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, 24-27, and 29 above, and further in view of Multitask Operating System for Automix® Compounders Version 2.30; Baxter May 1999.

Lewis et al. does not specifically recite that the pharmaceutical components comprises groups consisting of lipids and sterile water.

Baxter discloses a method of operating or programming an apparatus for compounding in which the patient and prescription data, performance of compounding calculations, printing reports, and support of the nutritional solution is detailed.

Three levels of user passwords including Administrator, Pharmacist, and Technician manage access to the programs of the device. The device also requires that patient's profile be entered when creating a prescription. The profile includes such information as the patient's weight, age, name, as well as the patient type (adult, pediatric, neonate, etc.) (see 2-5). As seen on the display of page 2-16 one of the components may be sterile water and Lipids as given on page 2-19. Before the prescription of a patient is compounded and verified via password, a series of validity tests are performed to warn the user producing warnings for overfill, electrolyte, osmolarity, ingredient volume, patient weight, and calcium phosphate solubility (pages 2-24 – 2-26). As seen on pages 3-4 and 3-5 the phosphate additive is added before the

calcium additive. The device is also capable of maintaining history logs of the patients information.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that lipids and sterile water may be components of the pharmaceutical components for Baxter discloses that these are common components used in the development of nutritional needs for adult, neonatal, and pediatric patients.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Friswell et al., Whisenhunt, Jr. et al., Lebl et al., Bergh et al., disclose liquid handling systems.

Wang et al. and Ecker et al. disclose computer programs for monitoring reaction systems.

Guan et al. disclose bed reactor systems.

Ruediger et al. disclose organic compound synthesis systems.

Bosetto et al. disclose automated dialysis methods.

Hoff et al. discloses a process for automated monitoring of microingredient inventory used in the manufacture of medicated feed.

Ito et al. discloses a process and apparatus for preparing a mixture.

Margrey et al. discloses a remotely operated laboratory system.

Ebersole et al. and Holtzman discloses sample preparation devices.


Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
March 6, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700